

Food and Drug Administration, HHS

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basis as determined by the method in the Food Chemicals Codex, 3d Ed. (1981), p. 466, which is incorporated by reference.

(4) *Heavy metals (as Pb)*. Not more than 40 parts per million as determined by method II in the Food Chemicals Codex, 3d Ed. (1981), p. 512, which is incorporated by reference.

(5) *Arsenic (As)*. Not more than 3 parts per million as determined by the method in the Food Chemicals Codex, 3d Ed. (1981), p. 464, which is incorporated by reference.

(c) In accordance with § 184.1(b)(2), these ingredients are used in food only within the following specific limitations:

Category of food	Maximum level in food (percent glycyrrhizin content of food) (as served)	Functional use
Baked foods, §170.3(n)(1) of this chapter	0.05	Flavor enhancer, §170.3(o)(11) of this chapter; flavoring agent, §170.3(o)(12) of this chapter.
Alcoholic beverages, §170.3(n)(2) of this chapter	0.1	Flavor enhancer, §170.3(o)(11) of this chapter; flavoring agent, §170.3(o)(12) of this chapter; surface-active agent, §170.3(o)(29) of this chapter.
Nonalcoholic beverages, §170.3(n)(3) of this chapter	0.15	Do.
Chewing gum, §170.3(n)(6) of this chapter	1.1	Flavor enhancer, §170.3(o)(11) of this chapter; flavoring agent, §170.3(n)(12) of this chapter.
Hard candy, §170.3(n)(25) of this chapter	16.0	Do.
Herbs and seasonings, §170.3(n)(26) of this chapter	0.15	Do.
Plant protein products, §170.3(n)(33) of this chapter	0.15	Do.
Soft candy, §170.3(n)(38) of this chapter	3.1	Do.
Vitamin or mineral dietary supplements	0.5	Do.
All other foods except sugar substitutes, §170.3(n)(42) of this chapter. The ingredient is not permitted to be used as a nonnutritive sweetener in sugar substitutes.	0.1	Do.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[50 FR 21044, May 22, 1985, as amended at 54 FR 24899, June 12, 1989]

§ 184.1409 Ground limestone.

(a) Ground limestone consists essentially (not less than 94 percent) of calcium carbonate (CaCO₃) and is prepared by the crushing, grinding, and classifying of naturally occurring limestone.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 173, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52442, Nov. 18, 1983]

§ 184.1415 Animal lipase.

(a) Animal lipase (CAS Reg. No. 9001-62-1) is an enzyme preparation obtained from edible forestomach tissue of calves, kids, or lambs, or from animal pancreatic tissue. The enzyme preparation may be produced as a tissue preparation or as an aqueous extract. Its characterizing enzyme activity is that of a triacylglycerol hydrolase (EC 3.1.1.3).

(b) The ingredient meets the general requirements and additional requirements for enzyme preparations in the Food Chemicals Codex, 3d ed. (1981), p. 110, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave., NW., Washington, DC 20418, or may be examined at the Office of Premarket Approval (HFS-200), Food and Drug Administration, 200 C St.,

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SW., Washington, DC, and the Office of the Federal Register, 800 North Capitol St., NW., suite 700, Washington, DC.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as GRAS as a direct food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an enzyme as defined in §170.3(o)(9) of this chapter to hydrolyze fatty acid glycerides.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

[60 FR 32911, June 26, 1995]

§ 184.1420 Lipase enzyme preparation derived from *Rhizopus niveus*.

(a) Lipase enzyme preparation contains lipase enzyme (CAS Reg. No. 9001-62-1), which is obtained from the culture filtrate resulting from a pure culture fermentation of a nonpathogenic and nontoxigenic strain of *Rhizopus niveus*. The enzyme preparation also contains diatomaceous earth as a carrier. The characterizing activity of the enzyme, which catalyzes the interesterification of fats and oils at the 1- and 3-positions of triglycerides, is triacylglycerol lipase (EC 3.1.1.3).

(b) The ingredient meets the general requirements and additional requirements for enzyme preparations in the monograph on Enzyme Preparations in the "Food Chemicals Codex," 4th ed. (1996), pp. 133 and 134, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe as a direct human food ingredient is based upon the following

current good manufacturing practice conditions of use:

(1) The ingredient is used as an enzyme as defined in §170.3(o)(9) of this chapter for the interesterification of fats and oils.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

[63 FR 24419, May 4, 1998]

§ 184.1425 Magnesium carbonate.

(a) Magnesium carbonate (molecular formula approximately $(\text{MgCO}_3)_4 \cdot \text{Mg}(\text{OH})_2 \cdot 5\text{H}_2\text{O}$, CAS Reg. No. 39409-82-0) is also known as magnesium carbonate hydroxide. It is a white powder formed either by adding an alkaline carbonate (such as sodium carbonate) to a solution of magnesium sulfate or by carbonation of a slurry of magnesium hydroxide followed by boiling of the resulting magnesium carbonate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 177, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an anticaking and free-flow agent as defined in §170.3(o)(1) of this chapter; a flour treating agent as defined in §170.3(o)(13) of this chapter; a lubricant and release agent as defined in §170.3(o)(18) of this chapter; a nutrient supplement as defined in §170.3(o)(20) of this chapter; a pH control agent as defined in §170.3(o)(23) of this chapter; a processing aid as defined in §170.3(o)(24) of this chapter; and a synergist as defined in §170.3(o)(31) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice.